Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–12657 Filed 5–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Facilitating Antibacterial Drug Development for Patients With Unmet Need and Developing Antibacterial Drugs That Target a Single Species Media; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding antibacterial drug development for patients with unmet need and developing antibacterial drugs that target a single species. FDA is interested in discussing the scientific challenges pertaining to such development programs, including enrollment challenges, clinical trial designs, and trial population. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. government Agencies, public health organizations, academic experts, and industry on various aspects of drug development for new antibacterial drugs for patients with unmet need and new antibacterial drugs that target a single species. The input from this public workshop will also help in developing topics for future discussion.

DATES: The public workshop will be held on July 18, 2016, from 8:30 a.m. to 5 p.m. and July 19, 2016, from 8:30 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221 Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding antibacterial drug development for patients with unmet need and developing antibacterial drugs that target a single species. Discussions will focus on potential development pathways, aspects of clinical trials including patient population, trial designs, and endpoints, and the role of clinical trial networks in antibacterial drug development.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to *unmetneed2016@fda.hhs.gov.* Persons without access to the Internet can call 301–796–1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Agenda: The workshop draft Agenda will be made available at: *http://wwwfda.gov/Drugs/NewsEvents/ucm497650.htm* at least 2 days prior to the meeting. The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* Transcripts will also be available on the Internet at: *http://wwwfda.gov/Drugs/NewsEvents/ucm497650.htm* approximately 45 days after the workshop.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12684 Filed 5–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on August 10, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Patricio G. Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993–0002, *Patricio.Garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* On August 10, 2016, the committee will discuss, make recommendations, and

vote on information regarding a de novo request for the SEEKER Newborn Screening System (SEEKER System), by Baebies, Inc. The SEEKER System consists of the SEEKER Analyzer, the SEEKER 4-Plex Assay Kit, the SEEKER Cartridges, the Spot Logic software, and quality control materials; it uses digital microfluidic technology to measure multiple lysosomal enzymatic activities quantitatively from newborn dried blood spot specimens. The proposed Indication for Use for the SEEKER System device, as stated in the de novo request, is as follows:

The SEEKER System is intended for quantitative measurement of the activity of multiple lysosomal enzymes from newborn dried blood spot specimens. Reduced activity of these enzymes may be indicative of a lysosomal storage disorder. The enzymes measured using the SEEKER 4-Plex Assay Kit and their associated lysosomal storage disorder are listed in the following table.

Enzyme (abbreviation)	Disorder
α-L-iduronidase (IDUA)	Mucopolysaccharidosis Type I (MPS I) disease.
α-D-glucosidase (GAA)	Pompe disease.
β-glucocerebrosidase (GBA)	Gaucher disease.
α-D-galactosidase A (GLA)	Fabry disease.

Reduced activity for any of the four enzymes must be confirmed by other confirmatory diagnostic methods.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 3, 2016. On August 10, 2016, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 26, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 27, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Sequencing Quality Control II; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Sequencing Quality Control II.'' The purpose of the public workshop is to define the scope of project and study designs, and solicit participation of DNA sequencing community and stakeholders for data generation, management, analysis, and interpretation.

DATES: The public workshop will be held on September 13 and 14, 2016, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at Wilson Hall, Bldg. 1, National Institutes of Health (NIH), 31 Center Dr., Bethesda, MD 20892. Entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center where routine security check procedures will be performed. For parking and security information, please refer to *https://www.nih.gov/about-nih/visitor-information/campus-access-security.*

FOR FURTHER INFORMATION CONTACT: Weida Tong, National Center for Toxicological Research (NCTR), Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7142, FAX: 870–543–7854, *weida.tong@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA's Critical Path Initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*) identifies pharmacogenomics as a key opportunity in advancing medical product development and personalized medicine. FDA has issued the ''Guidance for Industry: Pharmacogenomic Data Submissions'' (*http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079849.pdf*) to facilitate scientific progress in the field of pharmacogenomic data integration in drug development and medical diagnostics. Microarrays represent a core technology in